



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-23BJ; Docket No. CDC-2022-0139]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled U.S. National Authority for Containment of Poliovirus (U.S. NAC) Data Collection Tools. Data collection will capture information relating to a poliovirus containment breach or incident at a U.S. facility and will assist the U.S. NAC in the initial stages of the investigation into the breach, and ensure that facilities have programs in place that align with global poliovirus eradication initiative.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2022-0139 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

U.S. National Authority for Containment of Poliovirus Data
Collection Tools - New - Center for Preparedness and Response
(CPR), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

The role of the National Authority for Containment of Poliovirus (U.S. NAC) is to ensure that the requirements established in the World Health Organization (WHO) Global Action Plan (GAP) III/IV standard are effectively implemented and maintained in facilities working with or storing infectious poliovirus or potentially infectious materials.

Risk assessments following an incident are a critical component for adequate application of the GAP standard. To support risk assessment activities, the "Facility Incident Reporting Form for Poliovirus Release and Potential Exposure" and the "Facility Incident Reporting Form for Poliovirus Theft or Loss" was created for facilities to capture and submit incident information to the U.S. NAC. These forms will not only address the biosafety and biosecurity containment emergency elements of the GAP standard, but will also inform the U.S. NAC risk assessments, and thereby guide CDC's determination of the emergency response level and direction.

The information collected in the "Personal Protective Equipment Survey for Laboratories" will assist the CDC, U.S. NAC and National Institute for Occupational Safety and Health

(NIOSH) with developing guidance and recommendations for personal protective equipment (PPE) selection and use in support of poliovirus containment as well as identify laboratory PPE commonly used to evaluate laboratory PPE performance characteristics in testing studies.

Information collected in the "Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist" will aid U.S. facilities in preparing for an audit to obtain a poliovirus certificate of containment.

Data collected from the "Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire" will collect additional information on poliovirus materials held by a U.S. facility, their work activities, and facility features.

The "Poliovirus Containment Sampling Plan and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States" will collect information to assess poliovirus essential facility's wastewater system, the primary safeguards to reduce and control the release of poliovirus from the facility. In addition, it will verify the safeguards of local wastewater utilities that receive wastewater from the PEF.

OMB approval is sought for three years. The estimated annualized burden for this information collection is 72 hours. There is no cost to respondents other than their time.

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Release or Potential Exposure	10	1	45/60	8
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Theft or Loss	10	1	45/60	8
Facility Staff/Leadership	PPE Survey for Laboratories	10	1	90/60	15
Facility Staff/Leadership	GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire	10	1	90/60	15
Facility Staff/Leadership	GAP Facility Assessment Checklist	10	1	1	10
Facility Staff/Leadership	The Poliovirus Containment Sampling Plan and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States	10	1	90/60	15
Total					72

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2022-26890 Filed: 12/9/2022 8:45 am; Publication Date: 12/12/2022]